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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,038	03/28/2001	Lorna Strachan	11000.1037c3	1046

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/31/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,038

Applicant(s)

STRACHAN

Examiner

Ruixiang Li

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-29. Claims 1, 2 and 9-11 present in each group are drawn to different polypeptides and compositions comprising the polypeptides, classified in class 530, subclass 350.

Groups 30-57. Claims 3-8 and 12 present in each group are drawn to different polynucleotides, expression vectors, host cells, and compositions comprising the polynucleotides, classified in class 536, subclass 23.5, and class 435, subclasses 320.1, 325.

Groups 58-86. Claims 13-22 are drawn to methods of disorder treatment using polypeptides, classified in class 514, subclass 2.

Group 87-114. Claims 13-16, 19, and 20 are drawn to methods of disorder treatment using polynucleotides, classified in class 514, subclass 44.

Please note that Claims 13-16, 19, and 20 are present in all Groups 58-114 because these claims recite the use of both polypeptides and polynucleotides in disorder treatment.

2. This application has 114 claimed inventions as indicated by Groups 1-114. The inventions are distinct, each from the other for the following reasons. The 29 polypeptides of Groups 1-29 and the 28 polynucleotides of Groups 30-57 as indicated by their SEQ ID NOS are distinct, each from the other, because each

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individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

3. Inventions 1-29 are unrelated to Inventions 30-57. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case, the different inventions are drawn to completely different products, polypeptides and polynucleotides. These molecules have completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.
4. Inventions 58-86 are unrelated to Inventions 87-114. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. Inventions 58-86 are drawn to methods of disorder treatment using polypeptides whereas Inventions 87-114 are drawn to methods of disorder treatment using entirely different compositions, polynucleotides. The two methods are exclusive.
5. Inventions 1-29 are related to Inventions 58-86 as product and process of use. The invention can be shown to be distinct if either or both of the following can be shown:

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(1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the polypeptide may be used in a materially different process such as immunization of an animal to produce an antibody.

6. Inventions 30-57 are related to Inventions 87-114 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the polynucleotides may be used in a materially different process such as production of polypeptides.

7. Inventions 1-29 are unrelated to Inventions 87-114 because Inventions 1-29 are drawn to polypeptides whereas Inventions 87-114 are drawn to methods of disorder treatment using polynucleotides. Inventions 30-57 are unrelated to Inventions 58-86 because Inventions 30-57 are drawn to polynucleotides whereas Inventions 58-86 are drawn to methods of disorder treatment using polypeptides.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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9. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.
10. Inventions 58-86 contain claims directed to patentably distinct species of disorders: (a) an inflammatory disorder; (b) growth of blood vessels; (c) a disorder of the immune system; (d) cancer; (e) a tumor necrosis factor-mediated disorder; (f) a viral disorder; and (g) a fibroblast growth factor-mediated disorder. These disorders are entirely different disorders and require non-cohesive searches and considerations.
11. Inventions 87-114 also contain claims directed to patentably distinct species of disorders: (a) an inflammatory disorder; (b) growth of blood vessels; (c) a disorder of the immune system; (d) cancer; and (e) a viral disorder. These disorders are entirely different disorders and require non-cohesive searches and considerations.

Should applicants elect any invention of Groups 58-86 or Groups 87-114, applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
December 12, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600